

I claim:

[1. A medical device implantable in a heart, for treating arrhythmogenic sites in the heart, the device comprising:

a electrically inactive structure having an exposed surface and biocompatible at least over the exposed surface, said structure adapted to be chronically implanted into cardiac tissue within a region substantially adjacent to an arrhythmogenic site in a heart, and, when so implanted, altering conduction properties of the cardiac tissue within said region; and

wherein the structure incorporates a coupling means for releasably coupling the structure to a delivery device operable to deliver the structure to the region and implant the structure into the cardiac tissue, said coupling means operable to enable disengagement and removal of the delivery device after the structure is implanted.]

[2. The device of claim 1 wherein:

said structure is selected from a group consisting of helical bodies, stakes, and cages.]

[3. The device of claim 1 wherein:

said structure is formed of biocompatible materials selected from the group consisting of polytetrafluoroethylene, expanded polytetrafluoroethylene, polyester, polyurethane, silicon, platinum, iridium, titanium, and MP35N.]

[4. The device of claim 1 wherein:

said structure, at least over an outermost portion thereof that includes said exposed surface, is constructed of a biocompatible material selected from the group consisting of platinum black, titanium nitride, sintered platinum, roughened platinum, roughened MP35N, and roughened titanium, whereby the effective surface area of the structure is enhanced to augment electrical coupling of the structure and the cardiac tissue.]

[5. The device of claim 1 further including:

a delivery catheter releasably coupled at a distal end thereof to said structure by said coupling means,

adapted for intravascularly delivering the structure into the heart and to said region, and further operable at a proximal end thereof to at least partially embed the structure within said cardiac tissue at said region.]

[6. The device of claim 1 wherein:

said structure includes means for delivering a predetermined pharmacological agent to said cardiac tissue at said region, for further altering conduction properties of said tissue within said region.]

[7. The device of claim 6 wherein:

said structure includes a substrate coated with a non-conductive controlled release matrix less rigid than the substrate, with the controlled release matrix being at least partially embedded within said tissue when the structure is so implanted.]

[8. The device of claim 6 wherein:

said predetermined pharmacological agent is selected from a group consisting of anti-arrhythmic agents, angiogenic growth factors, anti-inflammatory agents, and their combinations.]

[9. The device of claim 6 wherein:

said structure includes a rigid core material forming a proximal head and a distal tip, and an insulative controlled release matrix covering the rigid core material between the head and the tip, to facilitate use of the structure for electrical mapping of said tissue when the structure is at least partially embedded into the tissue.]

[10. The device of claim 1 wherein:

said structure includes a hollow core and a plurality of apertures from the hollow core open to the outer surface of the structure, a proximally located head in fluid communication with the hollow core, and a tube coupled to the head for supplying a pharmacological agent to the hollow core via the head.]

[11. The device of claim 10 wherein:

said structure further includes a non-conductive controlled release matrix forming a coating over said apertures, for delivering said predetermined pharmacological agent to an innermost surface of said controlled release matrix.]

[12. A method of locally altering electrical activity in cardiac tissue at a selected site in the region of the heart, including:

measuring electrical activity in cardiac tissue, to identify a potential implantation site;

introducing a first electrically inactive and biocompatible implantable device into the region of the heart, and at least partially embedding said first implantable device into cardiac tissue at the site to effect an implantation.]

[13. The method of claim 12 further including:

after said implantation, performing a plurality of electrical measurements in cardiac tissue proximate the site and, based on results of said electrical measurements, performing at least one of the following sub-steps:

(i) determining that the implantation has successfully altered conduction properties as intended;

(ii) based on a determination that the implantation has not successfully altered conduction properties as intended, removing and repositioning the first implantable device; and

(iii) responsive to determining that the implantation has not successfully altered conduction properties as intended, embedding a second electrically inactive and biocompatible implantable device proximate the first implantable device and proximate said site.]

- [14. The method of claim 13 further including:
after said performing the plurality of electrical measurements and before performing said at least one substep, supplying a pharmacological agent via the first implantable device to cardiac tissue proximate the first implantable device.]
- [15. The method of claim 13 further including:
after said implantation and before said performing the plurality of electrical measurements, supplying a pharmacological agent via the first implantable device to cardiac tissue proximate the first implantable device.]
- [16. The method of claim 12 further including:
after said implantation of the first implantable device, supplying a pharmacological agent via the first implantable device to cardiac tissue proximate the first implantable device.]
- [17. The method of claim 16 wherein:
said supplying of a pharmacological agent comprises delivering the pharmacological agent from a source to the implantable device via a tube coupled to the implantable device.]
- [18. The method of claim 12 wherein:
said introducing the first implantable device comprises releasably attaching the first implantable device to a distal end of a catheter, using the catheter to intravascularly deliver the device to the implantation site, manipulating the catheter at a proximal end thereof to achieve said implantation, decoupling the catheter from the first implantable device and withdrawing the catheter after said implantation.]
- [19. An apparatus for locally modifying electrical action within a heart, comprising:
an implantable electrically inactive device including tissue penetration means and a coupling means; and
a delivery device having a proximal end and a distal end adapted for forming a releasable coupling to said implantable device via the coupling means, adapted for delivering the implantable device to a designated site in a heart and manipulable at said proximal end to implant the implantable device by causing said tissue penetration means to enter tissue; and further adapted for a decoupling from the implantable device and removal after the implantation, whereby the implantable device remains at the site and modifies electrical action at and proximate the site.]

- [20. The apparatus of claim 19 wherein:
said implantable device comprises a means to deliver
pharmacological agents to cardiac tissue at and proximate the site.]
- [21. An apparatus for locally modifying electrical action
within a heart, comprising:
a biocompatible, electrically inactive, implantable device
including a means for penetrating cardiac tissue to
effect an implantation of the implantable device at a
designated site in a heart, to modify electrical action in
the cardiac tissue at and proximate the site.]
- [22. The apparatus of claim 21 wherein:
the implantable device includes a non-conductive controlled
release matrix for supplying a predetermined
pharmacological agent to the cardiac tissue.]
- [23. The apparatus of claim 21 wherein:
the implantable device, at least over an outermost portion
thereof that includes an exposed surface, is constructed
of a biocompatible material selected from the group
consisting of platinum black, titanium nitride, sintered
platinum, roughened platinum, roughened MP35N and
roughened titanium, to enhance the effective surface
area of the exposed surface and thereby augment electrical
coupling of the implantable device and the cardiac
tissue.]
- [24. The apparatus of claim 21 further including:
a drug delivery catheter coupled to the implantable device
for delivering a pharmacological agent to the implantable
device, and wherein the implantable device
includes a hollow core in fluid communication with the
drug delivery catheter and open to an exterior of the
implantable device to supply the pharmacological
agent from the delivery catheter to the cardiac tissue.]
- [25. The apparatus of claim 21 further including:
a delivery catheter including a catheter distal end region
coupled to the implantable device, said delivery catheter
operable at a proximal end thereof to effect said
implantation; and
an electrode means at the catheter distal end for sensing
electrical action in the cardiac tissue before said
implantation, to facilitate locating the site.]
- [26. The apparatus of claim 25 wherein:
the catheter is releasably coupled to the implantable
device to allow a decoupling and withdrawal of the
delivery catheter after said implantation.]

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27. A process for delivering an angiogenic growth factor to the heart of a patient, including:

penetrating an element of a delivery device into heart tissue; and

delivering an angiogenic growth factor to the tissue through the element.

28. A process for treating the heart of a patient, including:

providing a catheter with a tissue penetrating element disposed at a distal end thereof;

inserting at least the distal end of the catheter into a chamber of the heart;

causing the penetrating element, while in the chamber of heart, to penetrate heart tissue;

and

delivering an angiogenic agent from the penetrating element to surrounding cardiac tissue.

29. An apparatus for locally modifying electrical action within the heart, comprising:

a biocompatible, electrically inactive device including an element for penetrating cardiac tissue to secure the device at a designated site in a heart, to modify electrical action in the cardiac tissue at the designated site; and

a catheter releaseably coupled to the device to allow use of the catheter to deliver the device to the designated site, and further to allow a withdrawal of the catheter after securing the device.

30. An apparatus for delivering a pharmacological agent to the heart, including:

a catheter body having a proximal end, a distal end, and adapted to convey a pharmacological agent toward the distal end; and

a tissue penetrating structure releasably coupled to the distal end of the catheter body and adapted to deliver the pharmacological agent from the catheter body into heart tissue.

31. A process for delivering an angiogenic agent to the heart, including:

providing a device having an element adapted to penetrate cardiac tissue;

inserting the device into a heart, and causing the element to penetrate tissue inside the heart; and

delivering an angiogenic agent through the penetrated element into surrounding tissue.

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